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10/585,612	07/11/2006	Seiichiro Miyahara	DK-US065157	7976
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HENKEL, DANIELLE B				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/585,612

Applicant(s)

MIYAHARA, SEIICHIRO

Examiner

DANIELLE HENKEL

Art Unit

1775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 5-16 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 5-16 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 7/16/10 has been entered.
2. Claims 5-16 are pending, of which 15-16 are new.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by ATWOOD (US 2002/0072112).
 - a. With respect to claim 16, ATWOOD teaches a temperature control device (thermal cycler) comprising a plurality of compartments (tubes) for holding microorganisms or cells (samples) (0095, 0098), and a heater and cooling unit making control of temperatures inside said cell parts (0099-0100, 0107-8),

wherein said control is corrected by using an ambient temperature that is the temperature of an environment in which the culture device itself (sample tubes) is installed (0110). ATWOOD teaches the temperature control device further comprising a thermometer (temperature sensor) measuring an ambient temperature (0110), a storage unit storing calibration data (central processing unit with memory, 0096); and a control unit (central processing unit, CPU) programming (setting) a target value for said temperatures inside said compartments (sample liquid), and managing (controlling) said sample block heater and said cooling unit to get the samples to the specified temperature (control of temperatures inside compartments (0202) and a calculation unit (CPU), wherein said calculation unit calculates a second target value from said ambient temperature and said target value, and said control unit controls said heater and said cooling unit with said second target value (0110, 0202). Additionally ATWOOD further discloses it is the sample target temperature that is user input and not the sample block temperature (202) and that the power and temperature of the sample block (second target value) is obtained/calculated according to a control algorithm (0195) by taking into account the user-defined temperature (target value), temperature sensor values including the ambient (0312, 0110, 0029) and calibration data (0096, 0323-0330). ATWOOD further discloses the controller calculates the sample temperature (temperature inside said compartments) which are then used by the control algorithm for controlling the heaters and cooling unit to achieve the user set target temperature and that

the controller compares the calculated sample temperature to the desired target temperature (0204, 0232, 0312)

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 5, 9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over ATWOOD (US 2002/0072112) in view of DEAN (WO 89/09437).

b. With respect to claims 5 and 15, ATWOOD teaches a temperature control device (thermal cyclor) comprising a plurality of compartments (tubes) for holding microorganisms or cells (samples) (0095, 0098), and a heater and cooling unit making control of temperatures inside said cell parts (0099-0100, 0107-8), wherein said control is corrected by using an ambient temperature that is the temperature of an environment in which the culture device itself (sample tubes) is

installed (0110). ATWOOD teaches the temperature control device further comprising a thermometer (temperature sensor) measuring an ambient temperature (0110), a storage unit storing calibration data (central processing unit with memory, 0096); and a control unit (central processing unit, CPU) programming (setting) a target value for said temperatures inside said compartments (sample liquid), and managing (controlling) said sample block heater and said cooling unit to get the samples to the specified temperature (control of temperatures inside compartments (0202). Additionally ATWOOD further discloses it is the sample target temperature that is user input and not the sample block temperature (202) and that the power and temperature of the sample block (second target value) is obtained/calculated according to a control algorithm (0195) by taking into account the user-defined temperature (target value), temperature sensor values including the ambient (0312, 0110, 0029) and calibration data (0096, 0323). ATWOOD further discloses the controller calculates the sample temperature (temperature inside said compartments) which are then used by the control algorithm for controlling the heaters and cooling unit to achieve the user set target temperature and that the controller compares the calculated sample temperature to the desired target temperature (0204, 0232, 0312), but does not explicitly disclose a relationship between the target temperature and the temperature inside the compartments being used as data to calculate the second target value. However, DEAN discloses reaction temperature control comprising reaction tubes (compartments holding cells), a

lamp and fan (heater and cooling unit), temperature sensor for the temperature of the environment, a programmable microprocessor (control unit) with ROM and RAM (memory storage unit) (Pages 5-7, 12) in which the sensor is used as a remote sensor and the temperature control is programmed with an equation that relates the amount of heating by the lamp (second target value) with the absolute required temperature (target) and the differential of the required temperature from the actual temperature (relationship, calibration data) where the sample temperature/ actual temperature is also calculated by an equation related to a setting for the plate temperature (ambient temperature) (Page 15). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of ATWOOD to include calculating the second target value using a relationship between the target and actual/sample temperature as taught by DEAN because it provides a good sample control, and the temperature of the phial (compartment) lags behind the plate temperature, reaching equilibrium much later so using phial temperature information the controller can operate to produce an improved time response for the temperature profile of the sample, thus reducing cycle times (Pages 13-15).

c. With respect to claim 9, ATWOOD teaches a temperature control device (thermal cycler) comprising a plurality of compartments (tubes) for holding microorganisms or cells (samples) (0095, 0098), and a heater and cooling unit making control of temperatures inside said cell parts (0099-0100, 0107-8), wherein said control is corrected by using an ambient temperature that is the

temperature of an environment in which the culture device itself (sample tubes) is installed (0110). ATWOOD teaches the temperature control device further comprising a thermometer (temperature sensor) measuring an ambient temperature (0110), a storage unit storing calibration data (central processing unit with memory, 0096); and a control unit (central processing unit, CPU) programming (setting) a target value for said temperatures inside said compartments (sample liquid), and managing (controlling) said sample block heater and said cooling unit to get the samples to the specified temperature (control of temperatures inside compartments (0202) and a calculation unit (CPU), wherein said calculation unit calculates a second target value from said ambient temperature and said target value, and said control unit controls said heater and said cooling unit with said second target value (0110, 0202). Additionally ATWOOD further discloses it is the sample target temperature that is user input and not the sample block temperature (202) and that the power and temperature of the sample block (second target value) is obtained/calculated according to a control algorithm (0195) by taking into account the user-defined temperature (target value), temperature sensor values including the ambient (0312, 0110, 0029) and calibration data (0096, 0323). ATWOOD further discloses the controller calculates the sample temperature (temperature inside said compartments) which are then used by the control algorithm for controlling the heaters and cooling unit to achieve the user set target temperature and that the controller compares the calculated sample temperature to the desired target

temperature (0204, 0232, 0312), but does not explicitly disclose a relationship between the target temperature and the temperature inside the compartments being used as data to calculate the second target value. However, DEAN discloses reaction temperature control comprising reaction tubes (compartments holding cells), a lamp and fan (heater and cooling unit), temperature sensor for the temperature of the environment, a programmable microprocessor (control unit) with ROM and RAM (memory storage unit) (Pages 5-7, 12) in which the sensor is used as a remote sensor and the temperature control is programmed with an equation that relates the amount of heating by the lamp (second target value) with the absolute required temperature (target) and the differential of the required temperature from the actual temperature (relationship, calibration data) where the sample temperature/ actual temperature is also calculated by an equation related to a setting for the plate temperature (ambient temperature) (Page 15). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of ATWOOD to include calculating the second target value using a relationship between the target and actual/sample temperature as taught by DEAN because it provides a good sample control, and the temperature of the phial (compartment) lags behind the plate temperature, reaching equilibrium much later so using phial temperature information the controller can operate to produce an improved time response for the temperature profile of the sample, thus reducing cycle times (Pages 13-15).

8. Claims 6-7, and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over ATWOOD (US 2002/0072112) in view of DEAN (WO 89/09437) and further in view of SCHAPER (US 5802856).

a. With respect to claim 6, ATWOOD discloses a multi-zone heater thermally connected to a thermal conducting block (0107, 0117), but does not explicitly disclose two heater lines with the plurality of thermal conductors. However, SCHAPER teaches a temperature control device in which the heater comprises a first and second line in contact with a thermally conductive plate (Column 11, lines 30-41 and Figure 17). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of modified ATWOOD to include the two heater lines contacting thermal conductors as taught by SCHAPER because it allows for independently controllable heating zones that allows for thermally cycling a substrate without requiring movement (Column 11, lines 30-41 and Column 2, lines 23-34). The combination of ATWOOD, DEAN and SCHAPER does not explicitly disclose a plurality of thermal conductors. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a plurality of thermal conductors, since it has been held that mere duplication of the essential working part of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

b. With respect to claim 7, ATWOOD discloses a multi-zone heater thermally connected to a thermal conducting block (0107, 0117), but does not explicitly

disclose two heater lines with the plurality of thermal conductors. However, SCHAPER teaches a temperature control device in which the heater comprises a first and second line in contact with a thermally conductive plate (Column 11, lines 30-41 and Figure 17). SCHAPER also teaches the thermal conducting areas are controlled to different temperatures from each other by each heater line (Column 12, lines 1-13). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of modified ATWOOD to include the two heater lines contacting thermal conductors as taught by SCHAPER because it allows for independently controllable heating zones that allows for thermally cycling a substrate without requiring movement (Column 11, lines 30-41 and Column 2, lines 23-34). The combination of ATWOOD, DEAN and SCHAPER does not explicitly disclose a plurality of thermal conductors. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a plurality of thermal conductors, since it has been held that mere duplication of the essential working part of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

c. With respect to claim 10, ATWOOD discloses a multi-zone heater thermally connected to a thermal conducting block (0107, 0117), but does not explicitly disclose two heater lines with the plurality of thermal conductors. However, SCHAPER teaches a temperature control device in which the heater comprises a first and second line in contact with a thermally conductive plate

(Column 11, lines 30-41 and Figure 17). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of modified ATWOOD to include the two heater lines contacting thermal conductors as taught by SCHAPER because it allows for independently controllable heating zones that allows for thermally cycling a substrate without requiring movement (Column 11, lines 30-41 and Column 2, lines 23-34). The combination of ATWOOD, DEAN and SCHAPER does not explicitly disclose a plurality of thermal conductors. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a plurality of thermal conductors, since it has been held that mere duplication of the essential working part of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

d. With respect to claim 11, ATWOOD discloses a multi-zone heater thermally connected to a thermal conducting block (0107, 0117), but does not explicitly disclose two heater lines with the plurality of thermal conductors. However, SCHAPER teaches a temperature control device in which the heater comprises a first and second line in contact with a thermally conductive plate (Column 11, lines 30-41 and Figure 17). SCHAPER also teaches the thermal conducting areas are controlled to different temperatures from each other by each heater line (Column 12, lines 1-13). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of modified ATWOOD to include the two heater lines contacting thermal conductors

as taught by SCHAPER because it allows for independently controllable heating zones that allows for thermally cycling a substrate without requiring movement (Column 11, lines 30-41 and Column 2, lines 23-34). The combination of ATWOOD, DEAN and SCHAPER does not explicitly disclose a plurality of thermal conductors. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a plurality of thermal conductors, since it has been held that mere duplication of the essential working part of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

9. Claims 8, and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over ATWOOD (US 2002/0072112) in view of DEAN (WO 89/09437) further in view of SCHAPER (US 5802856) and further in view of BANDO (US 6626236).

a. With respect to claim 8, ATWOOD discloses a multi-zone heater thermally connected to a thermal conducting block (0107, 0117), but does not explicitly disclose two heater lines with the plurality of thermal conductors. However, SCHAPER teaches a temperature control device in which the heater comprises a first and second line in contact with a thermally conductive plate (Column 11, lines 30-41 and Figure 17). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of modified ATWOOD to include the two heater lines contacting thermal conductors as taught by SCHAPER because it allows for independently controllable heating

zones that allows for thermally cycling a substrate without requiring movement (Column 11, lines 30-41 and Column 2, lines 23-34). The combination of ATWOOD, DEAN and SCHAPER does not explicitly disclose a plurality of thermal conductors. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a plurality of thermal conductors, since it has been held that mere duplication of the essential working part of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. SCHAPER also teaches first and second thermometers (sensors) for one of the first and one of the second thermal conductors (Column 11, lines 51-67, Figure 21) and that each set of thermal conductors (plate regions) is equal in thermal capacity (Column 11, lines 30-41). The combination of ATWOOD, DEAN and SCHAPER do not explicitly disclose the first and second thermal conductors being different from each other in thermal capacity. However, BANDO H teaches a temperature control unit in which the heater comprises heat wires contacting thermal conductors (plate zones) that differ from each other in thermal capacity (Column 5, lines 19-33). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the multi-zone heater of ATWOOD, DEAN and SCHAPER to include the thermal conductors differing from each other in thermal capacity as taught by BANDO H because it is effective to segment the thermal conductors into zones to independently control the their temperatures (Column 2, lines 64-67).

b. With respect to claim 12, ATWOOD discloses a multi-zone heater thermally connected to a thermal conducting block (0107, 0117), but does not explicitly disclose two heater lines with the plurality of thermal conductors. However, SCHAPER teaches a temperature control device in which the heater comprises a first and second line in contact with a thermally conductive plate (Column 11, lines 30-41 and Figure 17). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of ATWOOD and DEAN to include the two heater lines contacting thermal conductors as taught by SCHAPER because it allows for independently controllable heating zones that allows for thermally cycling a substrate without requiring movement (Column 11, lines 30-41 and Column 2, lines 23-34). The combination of ATWOOD, DEAN and SCHAPER does not explicitly disclose a plurality of thermal conductors. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a plurality of thermal conductors, since it has been held that mere duplication of the essential working part of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. SCHAPER also teaches first and second thermometers (sensors) for one of the first and one of the second thermal conductors (Column 11, lines 51-67, Figure 21) and that each set of thermal conductors (plate regions) is equal in thermal capacity (Column 11, lines 30-41). The combination of ATWOOD, DEAN and SCHAPER does not explicitly disclose the first and second thermal conductors being different from each other in thermal capacity.

However, BANDO H teaches a temperature control unit in which the heater comprises heat wires contacting thermal conductors (plate zones) that differ from each other in thermal capacity (Column 5, lines 19-33). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the multi-zone heater of modified to include the thermal conductors differing from each other in thermal capacity as taught by BANDO H because it is effective to segment the thermal conductors into zones to independently control the their temperatures (Column 2, lines 64-67).

c. With respect to claim 13, SCHAPER teaches the second heater line is provided on an outer edge side of said heater than first heater line is (Figure 17). BANDO H teaches the first and second thermal conductors include heat blocks provided for the heater lines (Column 5, lines 19-33, Figure 1).

10. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over ATWOOD (US 2002/0072112) in view of DEAN (WO 89-09437) as applied to claims 5, and 9, in view of HAGA (JP 2003-235544) and over ATWOOD (US 2002/0072112) in view of DEAN (WO 89-09437) in view of SCHAPER (US 5802856) as applied to claims 6-7, and 10-11 above, further in view of HAGA (JP 2003-235544) and over ATWOOD (US 2002/0072112) in view of DEAN (WO 89-09437) in view of SCHAPER (US 5802856) and BANDO H (US 6626236) as applied to claims 8, and 12-13 above and further in view of HAGA (JP 2003-235544).

a. With respect to claim 14, modified ATWOOD does not explicitly disclose the temperature control device comprising a sensor measuring a value that varies depending on metabolism. However, HAGA teaches a temperature control device that comprises a sensor for each cell part that measures a measurement value that varies depending on metabolism of said microorganisms or cells (0013-0015). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the temperature control device of modified ATWOOD, to include the sensor as taught by HAGA because it allows for maintaining the inside of a culture environment in optimal conditions for cultivating a cell (0002, 0010).

Response to Arguments

11. Applicant's arguments with respect to claims 5, 9 and their dependents have been considered but are moot in view of the new ground(s) of rejection of DEAN.

12. With respect to applicant's argument, page 10-11 regarding new claim 16, that the calibration data of ATWOOD isn't associated with the temperature of the ambient, the examiner respectfully disagrees. As disclosed by ATWOOD the calibration data is used to ensure precise measurements from the sensors (ambient temperature sensor) which are used in the calculation of the second target value (relationship) (0323-0332) and that the calibration data is used for precise calculations of the heater power delivered (second target value) (0995).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIELLE HENKEL whose telephone number is (571)270-5505. The examiner can normally be reached on Mon-Thur: 11am-8pm, Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on 571-272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DANIELLE HENKEL/
Examiner, Art Unit 1775

/Michael A Marcheschi/
Supervisory Patent Examiner, Art
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